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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* SCOTT W. WENZEL, DAVID WILLIAM KOENIG,  
DOUGLAS R. HOFFMAN, CANDACE DYAN KRAUTKRAMER,  
BRIAN THOMAS, CHERYL MOCADLO, and CHELSEA MAGIN

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Appeal 2016-007602<sup>1</sup>  
Application 11/957,169  
Technology Center 1600

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Before ERIC B. GRIMES, RICHARD M. LEOVITZ, and  
RYAN H. FLAX, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to a formulation for promoting skin cleanliness and health. The Examiner rejected the claims under 35 U.S.C. § 103 as obvious. We have jurisdiction under 35 U.S.C. § 6(b). The rejections are affirmed.

STATEMENT OF THE CASE

Appellants appeal from the Examiner's rejections of claims 1, 10–16, and 20–39 under pre-AIA 35 U.S.C. § 103(a) as obvious. The Examiner set

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<sup>1</sup> The Appeal Brief page 1 (“Appeal Br.”) (dated Jan. 13, 2016) lists Kimberly-Clark Worldwide, Inc., as the real-party-in-interest.

forth six grounds of obviousness rejections over the claims. Final Action pages 4, 8, 9, 11, 16, 17 (“Final Act.”) (dated Aug. 14, 2015). Each rejection is over the same two publications, Minerath et al. (WO 2004/022117 A1, publ. Mar. 18, 2004) (“Minerath”) and SaNogueira et al. (US Patent No. 6,830,746 B2, pat. Dec. 14, 2004) (“SaNogueira”), with additionally cited publications to reach further limitations in the claims. All the rejections turn on the issue of whether it was obvious at the time of the invention to combine Minerath and SaNogueira.

There are two independent claims, claims 1 and 28. Claim 28 is representative and reproduced below:

28. A formulation for promoting skin cleanliness and health, the formulation comprising from about 1% to about 5% by total weight of the formulation of dimethicone; from about 3% by total weight of the formulation to about 9% by total weight of the formulation of glycerin; from about 0.5% by total weight of the formulation to about 3% by total weight of the formulation of Vitamin E acetate; from about 1% by total weight of the formulation to about 5% by total weight of the formulation of Nylon-12; a pharmaceutically acceptable carrier; and from about 0.5% by total weight of the formulation to about 15% by total weight of the formulation of at least one viscoelastic agent selected from the group consisting of polyethylene glycol 400 monolaurate, polyethylene glycol 600 monolaurate, polyethylene glycol 1000 monolaurate, polyethylene glycol 4000 monolaurate, polyethylene glycol 600 dilaurate, polyethylene glycol 600 lauryl ether, and combinations thereof.

## REJECTIONS

Claim 28 is directed to a formulation for promoting “skin cleanliness and health.” The formulation comprises: (1) dimethicone; (2) glycerin; (3) vitamin E; (4) Nylon-12; (5) a viscoelastic agent selected from a specifically

recited list of agents; and (6) a pharmaceutically acceptable carrier. The claim recites a weight percent range of the total weight of the formulation for each of components (1) to (5).

Claim 1 has the same six components as claim 28, but further requires (7) a first temperature modulator which is an insulating agent, and (8) a second temperature modulator which is a warming agent.

The Examiner found Minerath describes a moisturizing and lubricating composition for use on the bodyfacing surface of an absorbent product, such as an on inter-labial pad. Final Act. 4. The Examiner found that Minerath teaches a composition with (1) dimethicone; (2) glycerin; (3) vitamin E; (5) a viscoelastic agent of the claimed list; and (6) a pharmaceutically acceptable carrier, where each component is disclosed in amounts which are encompassed by or overlapping with the claimed amounts. *Id.* at 6, 7.

The Examiner acknowledged that Minerath does not disclose the presence of (4) nylon-12 in its composition, but found that SaNogueira describes a sunscreen lotion that contains nylon-12 to “provide an enhanced, silky, and smooth feeling to the skin.” *Id.* at 6. The Examiner determined it would have been obvious to one of ordinary skill in the art to use nylon-12 in Minerath’s composition to soften skin and prevent it “from drying out in the absence of an undesirable greasy feeling,” as taught by SaNogueira. *Id.* at 7.

For claim 1, the Examiner found that Minerath describes (7) a first temperature modulator, but not (8) a second temperature modulator selected from the claimed list of modulators. *Id.* at 12. However, the Examiner found that Kupper (WO 97/02273, publ. Jan. 23, 1997) describes a topical

composition with the same temperature modulator as in claim 1, and determined it would have been obvious to one of ordinary skill in the art to include it in Minerath's composition for its known and expected benefit. *Id.* at 13.

Temperature properties; claimed amounts

Appellants contend that the combination of Minerath and SaNogueira “neither discloses nor suggests combining the claimed elements let alone in the claimed concentration ranges – in order to achieve” the beneficial results described in the Specification. Appeal Br. 9. Appellants also contend that Minerath's composition is hydrophilic and solid at room temperature in contrast to the claimed formulation, which is not hydrophilic and not solid at room temperature. *Id.* at 10. Thus, Appellants argue that Minerath “is not a proper piece of art to start from for an obviousness rejection.” *Id.*

Appellants also argue that the skilled worker would not have combined Minerath with SaNogueira because SaNogueira “teaches a lotion that has characteristics (e.g., solid at room temperature, etc.) that conflict with the teachings of Minerath.” *Id.*

The claims do not limit the recited formulation to one that is not hydrophilic or solid at room temperature. Thus, Appellants' argument is not persuasive because the claims are not limited to a formulation with these properties. Appellants did not establish that the amounts of each component recited in the claims would necessarily result in a formulation which is not hydrophilic and not solid at room temperature. To the contrary, the Examiner found that Minerath describes a composition with the same components as in claim 1, and in amounts that encompass or overlap with

the claimed amounts, providing a reasonable basis to believe that the prior art formulation would have the same properties as claimed. Final Act. 6, 7. Appellants disputed that the recited amounts are described in Minerath (Appeal Br. 8), but did not identify an error in the Examiner's factual findings, which are supported by a preponderance of the evidence (Final Act. 5–7).

With respect to Appellants' contention that the teachings in Minerath and SaNogueira "conflict," the only conflicting property Appellants point to is "solid at room temperature" and Appellants inconsistently asserted that both publications teach their respective composition is solid at room temperature. Appeal Br. 10; Reply Br. 2. Appellants did not identify a disclosure in SaNogueira where such temperature/physical state properties could be found.

### Nylon-12

All the claims require nylon-12. Appellants contend there "is nothing in Minerath that would suggest to one having ordinary skill in the art" choosing nylon-12 from SaNogueira to achieve the benefits of the claimed formulation. Appeal Br. 10.

The Examiner found that it would have been obvious to have utilized nylon-12 as taught by SaNogueira to impart a silky and smooth feeling with a reasonable expectation of success. Final Act. 7. The Examiner's findings are supported by a preponderance of the evidence. Because both publications describe topical formulations, we agree with the Examiner that it would have been reasonable to expect that nylon-12 would be effective in Minerath's composition.

Appellants have not identified a defect in the Examiner's fact-finding or conclusions, but rather stated that Minerath did not provide a reason to use nylon-12 from SaNogueira. However, as indicated above, the reason that would have prompted the addition of nylon-12 into Minerath's composition is provided by SaNogueira: to impart a silky and smooth feeling. Final Act. 7. Consequently, absent evidence to the contrary, Appellants' arguments are unavailing.

### Claim 1

Appellants also contend that it would not have been obvious to have added the temperature modulator from Kupper to Minerath's composition because there is no "disclosure in Minerath that temperature modulation can be achieved with Appellants' claimed elements and/or that Appellants' claimed elements should or could be used [] in the compositions of Minerath." Appeal Br. 19.

Appellants' arguments are not persuasive. The Examiner found reason to add a temperature modulator, which had the claimed property of being a warming agent, to Minerath because "Kupper teaches that such warming agents improve the perceived efficacy of compositions and deliver pleasing aesthetics that result in consumer satisfaction." Final Act. 13. Appellants did not identify a flaw in the Examiner's findings or reasoning. As both Minerath and Kupper describe topical compositions (*id.*), it would have been reasonable to expect that Kupper's warming agent would be effective in Minerath's composition. Appellants did not provide evidence to the contrary or reason to have doubted such efficacy.

Do the results in Specification establish non-obviousness?

Appellants cited evidence in the Specification that “when the specifically claimed components are combined in the specifically claimed concentration ranges, the formulations result in a variety of critical, beneficial results, such as, for example, reduction of frictional force, increased conductance, decreased roughness and increased elasticity.”

Appeal Br. 9. Based on this evidence, Appellants contend they have “successfully proved the criticality of the claimed formulation components and concentration ranges, and, thus, have successfully rebutted any basis for an obviousness rejection based upon overlapping ranges of the prior art’s components.” *Id.* Specifically, Appellants state:

the formulations detailed in Table 2 of the specification as originally filed, when tested, resulted in reduction of frictional force and showed improved maximum force values (see, e.g., Table 3). Details of the other benefits and critical results of the aforementioned results (e.g., increased conductance, decreased roughness and increased elasticity) are described in detail in Examples 3 and 4.

*Id.*

Table 2 of the Specification lists 16 different lotions (lotions 1–16), each comprising glycerin, dimethicone, nylon-12, and vitamin E acetate, which correspond to four of the components of the formulation of claims 1 and 28. Spec. ¶ 194. Each component is represented by two different amounts (“wt.%”), which fall within the scope of the claim. *Id.* The Specification discloses that “Application of every lotion formulation to the Vitro Skin® substrate reduced the frictional force value between the treated Vitro Skin® substrate and the silk and the nonwoven spunbond test substrates.” *Id.* at ¶ 203. The Specification also discloses that “Application



of most lotion formulations to the Vitro Skin® substrate also reduced the frictional force between the treated Vitro Skin® substrate and the VitroSkin® test substrate.” *Id.* The results are summarized in Table 3 of the Specification. *Id.* at ¶ 204.

Table 3 compares the mean force values for lotions 1–16 to an untreated control. *Id.* The data does not persuade us of the non-obviousness of the claimed subject matter. To demonstrate that the claimed invention exhibits some superior property or advantage, it must be compared to the closest prior art. *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991); *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995); *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

In this case, Appellants do not provide evidence of a comparison to the closest prior art. All sixteen lotions, and the amounts of components in each one, are said by Appellants to fall within the scope of the claim. Appeal Br. 4–5. The comparison is with an “untreated” control, not with a composition described by Minerath which the Examiner characterized as the closest prior art. Ans. 7–8. Thus, while Appellants contend that the showing demonstrates the “criticality” of the claimed amounts to the properties of the formulation (*id.*), there is no comparison to show that the amounts in the claim are any better as compared to amounts outside the claimed range which are described in Minerath.

Moreover, Appellants must show criticality of a claimed range. “[It] is not inventive to discover the optimum or workable ranges by routine experimentation.’ *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). Only if the ‘results of optimizing a variable’ are ‘unexpectedly good’ can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620

(CCPA 1977).” *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997).

Criticality of the claimed range has not been demonstrated since there is no comparison to concentrations outside the claimed ranges.

Appellants contend that it is not necessary to make such a comparison because “the closest prior art does not provide any comparative examples for Appellants to test, as the closest prior art fails to disclose or suggest all of Appellants' claimed components and ranges.” Reply Br. 4. As discussed by the Examiner (Ans. 4), Appellants have not identified which of the four tested components is responsible for the properties Appellants argue confer beneficial results. Appellants cannot establish the claimed amounts in their formulations are critical to achieve the asserted beneficial properties without a comparison to a formulation comprising even one component in amounts that are outside of the claimed range. Without such comparative data, it cannot be discerned whether formulations outside the claimed range would also possess the asserted properties. Consequently, we agree with the Examiner that the data is insufficient to establish the non-obviousness of claimed subject matter.

The same deficiencies are found in Examples 4 and 5 of the Specification. As discussed by the Examiner, no comparisons were performed to formulations having concentrations outside the claimed ranges. Moreover, the Examiner provided evidence that the results obtained with glycerin, nylon-12, and vitamin E would have been expected based on the teachings in the prior art. Ans. 6–7. Appellants did not identify a flaw in the Examiner’s finding, but merely asserted the amounts demonstrated criticality. Reply Br. 5.

Appellants also state the combination of the cited references “merely lists broad ranges of some of the claimed components (e.g., 5-90% of a humectant) and does not list the claimed components ever in combination, in the specifically claimed ranges, let alone disclosing the benefits that can be achieved therefrom.” Reply Br. 5. However, it is well-established that, when there is a range disclosed in the prior art, and the claimed invention overlaps or falls within that range, there is a presumption of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004). While Appellants contend that the criticality of the claimed ranges have been established, no comparison has been made to formulations containing components in amounts outside the claimed ranges to determine whether such benefits are characteristic of the claimed range or would be possessed by formulations outside it.

In addition, the Specification indicates that not all formulations showed the beneficial properties, i.e., “most lotion formulations [but not all] to the Vitro Skin® substrate also reduced the frictional force between the treated Vitro Skin® substrate and the VitroSkin® test substrate.” Spec. ¶ 203 (emphasis and brackets added). Thus, even were beneficial results described, it does not appear that all formulations within the scope of the claim possess such properties. The results must also be “commensurate in scope with the degree of protection sought by the claimed subject matter.” *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005). Here, the results are not commensurate with the scope of the claims because Appellants seek protection for a genus of formulations, but it does not appear that all formulations within the genus possess the asserted properties.

For the foregoing reasons, we affirm the obviousness rejections of claims 1 and 28. Claims 10–16 and 29–39 fall with claims 1 and 28 because separate reasons for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(iv).

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED